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on January 6, 2009.

PATENT  
Docket No.: 022101-000230US  
Client Ref. No.: 21640-US3

TOWNSEND and TOWNSEND and CREW LLP

By: Megan McCoy  
/Megan McCoy/

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

YOUNG, Karen K. Y.

Application No.: 10/815,480

Filed: March 31, 2004

For: COMPOSITIONS AND METHODS  
FOR DETECTING CERTAIN  
FLAVIVIRUSES, INCLUDING  
MEMBERS OF THE JAPANESE  
ENCEPHALITIS VIRUS SEROGROUP

Customer No.: 41504

Confirmation No.: 8589

Examiner: Mosher, Mary E.

Art Unit: 1648

**REQUEST FOR RECONSIDERATION  
OF PATENT TERM ADJUSTMENT  
DETERMINATION  
UNDER 37 C.F.R. § 1.705(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.705(b), Applicants respectfully request reconsideration of the patent term adjustment determination. This request is accompanied by the fee set forth in §1.18(e) and a statement of facts as required under 37 C.F.R. § 1.705(b)(2).

In view of the following it is respectfully requested that Applicants be granted a minimum patent term adjustment of 913 days, with an additional term to be added if the patent issues after April 21, 2009 (which is the Tuesday prior to 28 weeks after the mailing date of the Notice of Allowance).

**Statement of Facts as required under 37 C.F.R. § 1.705(b)(2)**

The correct patent term adjustment is 913 days, not 36 days as stated on the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) mailed on October 9, 2008 with the Notice of Allowance.

The period of adjustment under § 1.702(a) is 362 days (“A delay”).

The period of adjustment under § 1.702(b) is to be determined when the instant application issues. The effective period of adjustment under 37 C.F.R. § 1.702(b) is 752 days (“B delay”).

The period adjustment under § 1.704(a) is 91 days (“applicant delay”).

The period of adjustment under § 1.703(f) is 1004 days.

**The Relevant Dates as Specified in 37 C.F.R. §§ 1.703(a)-(e) and the Adjustment Specified in 37 C.F.R. § 1.703(f)**

**1. § 1.703(a)**

Applicants submit that the Office did not correctly calculate the term adjustments to include the term adjustments that Applicants are entitled under 37 CFR § 1.703(a)(1). **Exhibit A**, the Patent Term Adjustment History retrieved from private PAIR and attached hereto, contains the “02-07-2006 Mail Notice of Restarted Response Period”. The Office incorrectly determined the end-point of the period of adjustment under § 1.702(a)(1) to be September 12, 2005, not February 7, 2006.

The attached **Exhibit B**, the Restriction Requirement mailed February 7, 2006, states on page 2 under “Detailed Action” that it replaces the previous restriction requirement. Therefore, the correct period of adjustment under § 1.703(a)(1) is 252 days. The relevant dates are shown below.

Filing Date	14-month Date	Date of 1 <sup>st</sup> Restriction Requirement	Days over 14 months (§ 1.703(a)(1))
March 31, 2004	May 31, 2005	February 7, 2006	252 days

Applicants acknowledge that the Office has correctly determined the adjustment under § 1.703(a)(3) to be 110 days as defined under § 154(b)(1)(A).

Date of Applicant Reply	4-month Date	Date of mailed PTO Response	Days over 4months (§ 1.703(a)(3))
May 8, 2007	September 8, 2007	December 27, 2007	110 days

Applicants, however, respectfully request an additional period of adjustment equal to the number of days, if any, in the period beginning on the day after the date that is four months after the date on which the issue fee will be paid and all outstanding requirements are satisfied and ending on the date the patent issues. *See*, 35 U.S.C. §154(b)(1)(A)(iv), 37 C.F.R. § 1.702(a)(4) and § 1.703(a)(6).

**2. § 1.703(b)**

The Office failed to issue a patent within three years of the actual filing date of the above-referenced application. The period of adjustment under 37 C.F.R. § 1.702(b) begins on the day after the date that is three years from the filing date of the instant application, March 31, 2007, and ends on the day the patent is issued. The Notice of Allowance was mailed on October 9, 2008. If the patent issues approximately 28 weeks from the mailing of the Notice of Allowance, the estimated date of issuance is April 21, 2009 (rounded to nearest Tuesday).

Thus, the effective period of adjustment under 37 C.F.R. § 1.702(b) is 752 days, i.e., from March 31, 2007 to April 21, 2009 as shown in the table below.

Filing Date	3-year Date	Date of Notice of Allowance	28-weeks from Notice of Allowance	Estimated days over 3 years through Issuance (§ 1.703(b)(1))
March 31, 2004	March 31, 2007	October 9, 2008	April 21, 2009	752 days

Applicants respectfully submit that at the time of the October 9, 2008 mailing of the Notice of Allowance, the instant application had been entitled to a period of adjustment under 37 C.F.R. § 1.702(b) of a minimum of 558 days. Applicants submit that the instant application will be entitled to additional adjustment days until the issuance of a letters U.S. Patent from the subject application.

**3. §§ 1.703(c)-(e)**

There are no relevant dates as specified under §§ 1.703(c)-(e)

**4. Overlapping periods under §§ 1.703(a)-(e)**

Applicants have calculated overlapping periods in accordance with *Wyeth v. Dudas* (Case No. 07-1492, D.D.C. 2008). Thus, the periods of delay under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §1.54(b)(1)(B) overlap only if they occur on the same calendar day or days.

There are 110 days of overlap between the periods of delay adjusted under § 1.703(a) and § 1.703(b). March 31, 2007 is the date that starts the period of adjustment that begins three years from the filing date of the instant application (*see* § 1.702(b)). The 110 days of adjustment from the Office under § 1.703(a)(3) occurs after March 31, 2007, which is the start date of type “B” delay. Therefore, while the 110 days is a type “A” delay, it overlaps with the type “B” delay since it covers the period of time from September 8, 2007 through December 27, 2007.

**5. § 1.703(f)**

The period of adjustment under 37 C.F.R. § 1.702(f) is as follows:

Type “A” delay:	362 days
Type “B” delay:	752 days
“A” and “B” overlap:	110 days
<u>Adjusted</u>	<u>1004 days</u>

As discussed above, Applicants respectfully request an additional period of adjustment equal to the number of days, if any, under 37 C.F.R. § 1.703(a)(6). Any such period of adjustment under 37 C.F.R. § 1.703(a)(6) begins on April 21, 2009 will not overlap with a period of adjustment under 37 C.F.R. § 1.702(b).

**Reduction of Period of Adjustment of Patent Term Under 37 C.F.R. §1.704**

The Office did not calculate the correct period of adjustment under § 1.704(a). The attached Patent Term Adjustment History (*see Exhibit A*) states that Applicant Delay is 178 days and shows two periods of time where the Applicants accrued delay time. The correct period of adjustment under § 1.704(a) is **91 days**, not 178 days for the reasons set forth below.

As described above under § 1.703(a), the Office incorrectly determined the initial 14-month deadline to be September 12, 2005, not February 7, 2006. Therefore, the Office further incorrectly allotted 87 days over the three month period allowed under § 1.704(b) for the Applicants' March 9, 2006 response to the February 7, 2006 Restriction Requirement. Applicants respectfully submit that this is in error since (1) the February 7, 2007 Restriction Requirement vacated the September 12, 2005 Restriction Requirement; (2) the March 9, 2006 response was less than three months from the February 7, 2006 mailing date; and (3) § 1.704(b) requires an Applicant reply period of greater than three months before accruing delay time.

**Terminal disclaimer**

The instant application is not subject to a terminal disclaimer.

**PATENT TERM ADJUSTMENT DETERMINATION**

Under *Wyeth v. Dudas* Decision:

Applicants respectfully request **991 days** of patent term adjustment, *i.e.*, [1004 days (A delay + B delay)] minus [110 days (overlap of “A” and “B” delay)] minus [91 days (applicant delay)]. Applicants are also entitled to any period of adjustment under 37 C.F.R. § 1.703(a)(6).

Absent *Wyeth v. Dudas* Decision:

As of the date (January 6, 2009) of the Issue Fee payment for the subject application, Applicants are entitled to a minimum of **556 days** of patent term adjustment, *i.e.*, [647 days (B delay as of 1/6/2009)] minus [91 days (applicant delay)]. In addition, Applicants are entitled to one additional day of patent term adjustment for each day it takes after January 6, 2009 to issue the letters patent from the subject application under 37 C.F.R. § 1.703(b).

Based on the foregoing, Applicants respectfully request reconsideration of the patent term adjustment determination.

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PATENT

Please charge the fee set forth in 37 C.F.R. §1.18(e) (\$200.00) to Deposit Order Account No. 20-1430. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 20-1430.

Respectfully submitted,



Matthew E. Hinsch  
Reg. No. 47,651

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10/815,480	COMPOSITIONS AND METHODS FOR DETECTING CERTAIN FLAVIVIRUSES, INCLUDING MEMBERS OF THE JAPANESE ENCEPHALITIS VIRUS SEROGROUP	12-23- 2008::16:32:48
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**Patent Term Adjustments**

Patent Term Adjustment (PTA) for Application Number: 10/815,480

Filing or 371(c) Date:	03-31-2004	USPTO Delay (PTO) Delay (days):	214
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	178
Post-Issue Petitions (days):	+0	Total PTA (days):	36
USPTO Adjustment(days):	+0	Explanation Of Calculations	

**Patent Term Adjustment History**

Date	Contents Description	PTO(Days)	APPL(Days)
10-09-2008	Mail Notice of Allowance		
10-08-2008	Document Verification		
09-29-2008	Notice of Allowance Data Verification Completed		
09-29-2008	Case Docketed to Examiner in GAU		
09-16-2008	CRF Is Good Technically / Entered into Database		
08-22-2008	New or Additional Drawing Filed		
09-16-2008	Date Forwarded to Examiner		
08-22-2008	Response after Ex Parte Quayle Action		
06-23-2008	Mail Ex Parte Quayle Action (PTOL - 326)		
06-19-2008	Ex Parte Quayle Action		
04-11-2008	Date Forwarded to Examiner		
03-18-2008	Response after Non-Final Action		
03-06-2008	Mail Examiner Interview Summary (PTOL - 413)		
02-25-2008	Examiner Interview Summary Record (PTOL - 413)		
12-27-2007	Mail Non-Final Rejection	110	
12-20-2007	Non-Final Rejection	⬆	
09-10-2007	Notice of Appeal Filed	⬆	
09-10-2007	Request for Extension of Time - Granted	⬆	
09-12-2007	Date Forwarded to Examiner	⬆	
05-08-2007	Amendment after Final Rejection	⬆	
08-23-2007	Case Docketed to Examiner in GAU		
03-09-2007	Mail Final Rejection (PTOL - 326)		
03-05-2007	Final Rejection		
12-20-2006	Date Forwarded to Examiner		
12-05-2006	Response after Non-Final Action		91
12-05-2006	Request for Extension of Time - Granted	⬆	
12-11-2006	Mail Examiner Interview Summary (PTOL - 413)	⬆	
11-30-2006	Examiner Interview Summary Record (PTOL - 413)	⬆	
06-05-2006	Mail Non-Final Rejection		⬆
05-30-2006	Non-Final Rejection		

EXHIBIT A -- cont'd

03-07-2005	Information Disclosure Statement considered	
09-07-2004	Information Disclosure Statement considered	
03-14-2006	Date Forwarded to Examiner	
03-09-2006	Response to Election / Restriction Filed	87
--> 02-07-2006	Mail Notice of Restarted Response Period <--	⬆
02-06-2006	Letter Restarting Period for Response (i.e. Letter re: References)	⬆
09-12-2005	Mail Restriction Requirement	104
09-08-2005	Requirement for Restriction / Election	⬆
04-01-2005	Case Docketed to Examiner in GAU	⬆
03-07-2005	Information Disclosure Statement (IDS) Filed	⬆
03-07-2005	Information Disclosure Statement (IDS) Filed	⬆
03-04-2005	Receipt of all Acknowledgement Letters	⬆
03-04-2005	Receipt of Acknowledgment Letter	⬆
11-23-2004	Agency Referral Letter Mailed	⬆
11-19-2004	Referred by L&R for Third-Level Security Review. Agency Referral Letter Generated	⬆
11-19-2004	Correspondence Address Change	⬆
11-19-2004	Auto Referred by PALM Pre Exam	⬆
09-07-2004	Reference capture on IDS	⬆
09-07-2004	Information Disclosure Statement (IDS) Filed	⬆
09-07-2004	Information Disclosure Statement (IDS) Filed	⬆
09-21-2004	IFW TSS Processing by Tech Center Complete	⬆
09-21-2004	Case Docketed to Examiner in GAU	⬆
07-22-2004	Preliminary Amendment	⬆
08-12-2004	Application Return from OIPE	⬆
08-12-2004	Application Return TO OIPE	⬆
08-12-2004	Application Dispatched from OIPE	⬆
08-12-2004	Application Is Now Complete	⬆
07-15-2004	Additional Application Filing Fees	⬆
07-15-2004	CRF Disk Has Been Received by Preexam / Group / PCT	⬆
07-15-2004	A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in	⬆
07-15-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	⬆
07-30-2004	CRF Is Good Technically / Entered into Database	⬆
05-18-2004	Notice Mailed--Application Incomplete--Filing Date Assigned	⬆
04-30-2004	Cleared by OIPE CSR	⬆
04-11-2004	IFW Scan & PACR Auto Security Review	⬆
03-31-2004	Initial Exam Team nn	⬆

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Close Window

EXHIBIT B



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,480	03/31/2004	Karen K.Y. Young	022101-000230US	8589

41504 7590 02/07/2006

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SAN FRANCISCO, CA 94111

EXAMINER

SALVOZA, M FRANCO G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## EXHIBIT B -- cont'd

## Office Action Summary

Application No.

10/815,480

Applicant(s)

YOUNG, KAREN K.Y.

Examiner

M. Franco Salvoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.  
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) ☐ Notice of Informal Patent Application (PTO-152)  
 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

After review of the previous Action, it was determined that upon further consideration that further restriction is appropriate for a thorough and complete examination. The Office regrets any inconvenience. The restriction set forth below replaces the previous one.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 51, 54 drawn to an oligonucleotide and composition comprising SEQ ID NO: 8, classified in class 536, subclass 22.1.
- II. Claims 9-15, 34-39, 52, 55, drawn to an oligonucleotide, kit and composition comprising SEQ ID NO: 15 (a fragment of SEQ ID NO:9) and SEQ ID NO: 74 (identical to SEQ ID NO:9), classified in class 536, subclass 22.1.
- III. Claims 16-27, 53, 56 drawn to an oligonucleotide, kit and composition comprising SEQ ID NO: 28 (identical to SEQ ID NO:16), classified in class 536, subclass 22.1.
- IV. Claims 28-33, 40-49, drawn to a kit comprising SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 16, classified in class 536, subclass 22.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d).

In the instant case, nucleotide sequences encoding different proteins and kits comprising

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different groups of nucleotide sequences are structurally distinct chemical compounds with separate utilities such as being used to probe or code for specific amino acid sequences. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR 1.141 et seq. (MPEP § 803.04).

Inventions I-III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Group IV does not rely on any one of the subcombinations for patentability, rather on the particular combination of elements. The subcombinations have separate utility such as for use in probes or to code for specific proteins.

***Species Election***

This application contains claims directed to the following patentably distinct species of the claimed invention:

If applicant elects Invention III, applicant must further elect:

One fluorescent moiety for claims 18, 19, 20;

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One quencher moiety for claims 22, 24 or a non-fluorescent quencher moiety for claims 22, 23.

If applicant elects Invention IV, applicant must further elect:

One fluorescent moiety for claims 41, 43 and 44;

One quencher moiety for claims 45 and 47 or a non-fluorescent quencher moiety for claims 45 and 46;

One thermostable DNA polymerase for claims 48 and 49.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct,

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applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the search required for Group IV is not co-extensive with the searches for Groups I-III, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
M. Franco Salvoza  
Patent Examiner

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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2/6/06